



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|-----------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST_NAMED_INVENTOR | ATTORNEY_DOCKET_NO. | CONFIRMATION_NO. |
| 10/044,636 | 10/19/2001 | Sidney T. Smith | FLM-5169 | 8615 |

7590 12/12/2003

MARK J. BUONAIUTO, ESQ.
BAXTER INTERNATIONAL INC.
LAW DEPARTMENT
ONE BAXTER PARKWAY, DF2-2E
DEERFIELD, IL 60015

EXAMINER

BISSETT, MELANIE D

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/044,636 | SMITH ET AL. | |
| | Examiner | Art Unit | |
| | Melanie D. Bissett | 1711 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 August 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-60 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 15 August 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0403.

4) Interview Summary (PTO-413) Paper No(s). _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____ .

1. The rejections based on Small, Jr. et al. as a primary reference have been withdrawn based on the applicant's amendment. However, all other rejections have been maintained. Furthermore, rejections based on new matter have been made as necessitated by amendment.

Information Disclosure Statement

2. The Information Disclosure Statement has been considered by the examiner to the extent that time allowed. Note that only those references relevant to examination of the present application should be submitted. The Rosenbaum reference has been stricken from the IDS since it is already of record.

Claim Rejections - 35 USC § 112

3. Claims 1-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. First, the claims now recite layers "consisting essentially of" certain polymers. It is the examiner's position that the specification gives no guidance as to which polymers would be included or excluded from such a recitation. The specification does not teach one of ordinary skill in the art which materials, when added to the layers, would have any affect on the outcome. Further, one skilled in the art considering the original

specification would not be guided to exclude any materials from the layers, provided the necessary polymers (polyester, polyamide, or ethylene copolymer) are present.

5. Second, the claims recite "having a DSC melting point of 100°C or lower". The specification gives no guidance to such a limitation. Although the applicant points to the specification's mention of Affinity or Exact polymers as suggestion for the limitation, no specific Affinity or Exact polymers are mentioned. One of ordinary skill in the art would not be guided by the specification to choose a polymer fitting such a limitation. Note that, although many of the polymers in the Affinity and Exact families have melting points lower than 100 °C, others do not (see data sheets for Affinity PL 1840 and Affinity PT 1409). Thus, the vague mention of Affinity or Exact polymers in the specification does not lead one to the limitation of a melting point lower than 100 °C.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 1-3, 6-10, 14-17, 46-49, 53-56, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbaum et al. as evidenced by Piper et al.
8. From a prior Office action:

Rosenbaum discloses a multi-layered structure for medical articles and containers, where the structure contains a skin layer, a barrier layer, and an RF layer (abstract; col. 3 lines 56-62). A core layer between the skin and RF layers comprises Tafmer™ ultra low density polyethylene (ULDPE) (col. 4 lines 48-57), a material noted by the applicant as an ethylene/α-olefin having a C₄₋₈ α-olefin. Piper teaches Tafmer™ ULDPE as prepared using a single-site catalyst (col. 6 lines 42-56). Suitable barrier layers include polyamide materials, which may be attached between the skin and RF layers by a tie layer (col. 5 lines 3-22). RF layers may also comprise ULDPE, having a density less than 0.90 g/cc (col. 6 lines 62-66). RF layers may also comprise polyamides,

Art Unit: 1711

preferably those resulting from a reaction of dimer fatty acids (col. 8 lines 12-35). Suitable tie layers include those cited by the applicant as modified polyolefin blends (col. 9 line 65-col. 10 line 4). Figure 7 shows a multi-layered article having an elastic modulus of 20 kpsi (col. 11 lines 14-17; table cols. 13-14). In this example, a 2.0-mil core layer comprising ULDPE is attached to a 5.0-mil RF layer comprising a dimer fatty acid-produced polyamide through two 0.5-mil polyolefin blend tie layers. No slip agents are mentioned in the example. The layers may be processed by co-extrusion or co-extrusion coating (col. 10 lines 40-43). The reference reports RF layers of 5-8 mils and tie layers of 0.2-1.0 mils (col. 8 lines 56-60; col. 9 line 65-col. 10 line 4).

Regarding the applicant's claims 2-3, it is the examiner's position that, when the limitations of claims 2-3 are read into claim 1, the first layer of claim 1 is still open to either a specific polyester or a *polyamide material*. Thus, since the reference teaches polyamide materials instead of polyester materials, claims 2-3 are still anticipated. If claims 2-3 were rewritten to limit the first layer to a polyester material (i.e., "wherein the first layer is a polyester ether"), the rejection of claims 2-3 using Rosenbaum et al. would be withdrawn.

9. Claims 1-10, 14-15, 17, 46-49, 54, and 56-60 are rejected under 35

U.S.C. 102(e) as being anticipated by Piper et al.

10. From a prior Office action:

Piper discloses a multi-layered film comprising an outer layer and a layer containing an ethylene/α-olefin interpolymer having a density of less than about 0.91 g/cc (abstract). The materials are used to make bags for foodstuffs (col. 2 lines 28-30). The outer layer contains up to 80% of another polymer, where polyamides and polyesters are both mentioned as possible blended polymers (col. 6 lines 5-16). The second layer includes a copolymer having a density most preferably less than about 0.900 g/cc (col. 6 lines 32-36) and prepared from a single-site catalyst (col. 6 lines 42-56). The reference notes the use of 1-butene, 1-hexene, and 1-octene as α-olefins (col. 6 lines 57-63). Thicknesses range from 0.001-0.1 mm (~0.04-4 mils) (col. 7 lines 22-31), where thicknesses of 4 mils are exemplified (examples 1-3). Piper further discusses the use of additional polyamide or polyester layers, where nylon-6, nylon-10, nylon-11, nylon-12, nylon-22, and nylon-610 are all mentioned as polyamide materials (col. 8 lines 17-47). Most preferred thicknesses of the polyamide or polyester layer range from 0.05-0.25 mm (~2-10 mils) (col. 8 lines 48-56). The multi-layered films may also contain tie layers (col. 8 lines 62-63). The reference exemplifies a tie layer thickness of 1.2 mils (examples 1-3). Films are co-extruded without the use of slip agents (examples 1-3).

Piper demonstrates several layer structures for the multi-layered films, many of which show a layer B (ethylene/α-olefin copolymer) attached to a layer D or D' (may be amide or ester) or attached to a layer E or E' (polyester or polyamide) (col. 9 lines 19-47). Tie layers may be used in

Art Unit: 1711

any structure. Thus, one skilled in the art would clearly envision the use of tie layers to adhere any of the given layers. The multi-layered films have a most preferred Young's modulus above 400 MPa (58,015 psi), but the reference encompasses a lower "preferred" modulus value of 200 MPa (29,007 psi) (col. 9 line 61-col. 10 line 4). Thus, the reference teaches elastic modulus values of below 60,000 psi.

Regarding the intended use for fabricating medical products, the reference does not seem to mention the use of the articles in medical products. However, the articles are capable for use in food wrapping and containers. It is the examiner's position that the articles are capable of use in medical applications, lacking evidence to the contrary.

Regarding the applicant's claims 2-3, it is the examiner's position that, when the limitations of claims 2-3 are read into claim 1, the first layer of claim 1 is still open to either a specific polyester or a polyamide material. Thus, when polyamide layers are used instead of polyester layers, claims 2-3 are still anticipated. If claims 2-3 were rewritten to limit the first layer to a polyester material (i.e., "wherein the first layer is a polyester ether"), the rejection of claims 2-3 using Piper et al. would be withdrawn.

11. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Shang et al.
12. From a prior Office action:

Shang discloses polymer films for fabricating flexible medical containers [0003] having a modulus of elasticity below 60,000 psi [0040]. The reference teaches layers containing ULDPE, preferably made from a single-site catalyst and an α -olefin having 4-8 carbon atoms [0042]. Skin layers may be attached to the polyolefin film, where a preferred skin layer comprises PCCE [0089]-[0090].

Regarding the applicant's claims 4-7, it is the examiner's position that, when the limitations of claims 4-7 are read into claim 1, the first layer of claim 1 is still open to either a specific polyamide or a polyester material. Thus, when polyester layers are used instead of polyamide layers, claims 4-7 are still anticipated. If claims 4-7 were rewritten to limit the first layer to a polyamide material (excluding polyester materials; i.e., "wherein the first layer is a polyamide and is selected from"), the rejection of claims 4-7 using Shang et al. would be withdrawn.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1711

14. Claims 10, 14-21, 25-31, 35-41, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shang et al. in view of Small, Jr. et al.

15. From a prior Office action:

Shang et al. applies as above, failing to mention the thickness and use of a tie layer in the invention. Small, Jr. discloses multi-layered structures for flexible medical packaging comprising an ethylene/α-olefin copolymer layer, an intermediate tie layer, and an exterior layer chosen from polyester, copolyester, polyamide, or polyolefin (col. 1 lines 39-62). Small, Jr. teaches that the multi-layered structures may be cast co-extruded by conventional techniques to form containers, pouches, and packages for medical purposes (col. 6 lines 50-65). Examples show ethylene/α-olefin layers having a thickness of 5.7-6.8 mils, a tie layer having a thickness of 0.46-1 mils, and an exterior layer having a thickness of 0.7-1.4 mils, where the thicknesses of the layers are known to affect the autoclavability and other properties of the film (col. 2 lines 29-46). Since the multi-layered structures of Shang share a common desired application and a need to stand up to autoclave sterilization [0040], it is the examiner's position that it would have been *prima facie* obvious to use Small, Jr.'s teaching as a guide for choosing layer thickness values which optimize autoclavability and mechanical properties of a multi-layered film.

Also, Small, Jr. teaches that the use of a tie layer between the polyamide or polyester layer and the ethylene/α-olefin layer serves to improve adhesion and prevent delamination of the layers of the structure (col. 2 lines 12-17). Therefore, it is the examiner's position that it would have been *prima facie* obvious to use a tie layer between the polyamide or polyester layer and the ethylene/α-olefin layer of Shang's invention to improve adhesion and prevent delamination of the multi-layered film.

Shang also does not seem to teach the applicant's claimed co-extrusion techniques. Small, Jr. teaches multi-layered films formed by cast co-extrusion without the use of slip agents. Because the multi-layered structures of Shang share a common layer structure and desired application, and because Small, Jr. teaches the conventionality of using such cast-coextrusion techniques, it is the examiner's position that it would have been *prima facie* obvious to use the cast-coextrusion technique taught by Small, Jr. without the use of slip agents in Shang's invention with the expectancy of beneficial results.

16. Claims 11-13 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbaum et al. in view of Adur et al.

17. From a prior Office action:

Art Unit: 1711

Rosenbaum applies as above, teaching the use of maleic anhydride-modified polyolefin tie layers (col. 9 line 65-col. 10 line 4) but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α -olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Rosenbaum's invention to improve the adhesive strength between the polyolefin and polar substrate.

18. Claims 11-13 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piper et al. in view of Adur et al.

19. From a prior Office action:

Piper applies as above, teaching the use of anhydride-modified polyolefin tie layers (examples) but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α -olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been prima facie obvious to use the adhesive blend of Adur's teaching in the composite of Piper's invention to improve the adhesive strength between the polyolefin and polar substrate.

20. Claims 11-13, 22-24, 32-34, 42-44, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shang et al. in view of Small, Jr. et al. as applied to claims 10, 14-21, 25-31, 35-41, and 45 above, and further in view of Adur et al.

21. From a prior Office action:

Shang and Small, Jr. apply as above, teaching the use of modified polyolefin tie layers (Small, Jr. examples) but failing to specify a blend of a modified polyethylene copolymer with a polyolefin polymer. Adur teaches adhesive blends of grafted polyethylene homopolymers or copolymers, LDPE or LLDPE, and a poly(α -olefin), where the blends have improved adhesive strength with both polyolefins and polar substrates (col. 1 lines 36-56; col. 2 lines 4-10). The adhesives can be applied to substrates and co-extruded to form a number of articles (col. 1 lines 57-68). Examples of specific composites are listed, including polyolefin/adhesive/nylon, polyolefin/adhesive/EVOH, and polyolefin/adhesive/polyester (col. 4 lines 15-27). Maleic anhydride is noted as a preferred modifying monomer (col. 2 lines 49-65; examples 40-41, at least). Therefore, it is the examiner's position that it would have been *prima facie* obvious to use the adhesive blend of Adur's teaching in the composite of Shang and Small, Jr. to improve the adhesive strength between the polyolefin and polar substrate.

Response to Arguments

22. In response to the applicant's arguments that the references do not teach the layers "consisting essentially of" the specific polymers, it is noted that the specification gives no guidance to excluding any materials. The specification also does not teach that blended polymers would have an adverse affect on the invention. Note that the transitional phrase "consisting essentially of" limits the claim to those recited polymers and to those that would not materially affect the basic and novel characteristics of the claimed invention. See MPEP 2111.03. The phrase does not limit the claims to exclude any materials which would affect the product but only to exclude those materials which would ***materially*** affect the inventive concept taught in the specification. The applicant has not provided sufficient evidence to show that blended materials, including those of the cited references, would materially affect the desired properties of the invention.

23. Regarding the Shang reference, the applicant has argued that the reference *is* commonly assigned to the present applicant. This does not constitute a proper statement of common ownership because the statement provided by the applicant does not specify that the inventions were commonly owned *at the time of the invention*. See MPEP 706.02(I)(1)-706.02(I)(3). Thus, the rejections based on 35 USC 103 have been maintained.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie D. Bissett whose telephone number is (571) 272-1068. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

mdb


RABON SERGENT
PRIMARY EXAMINER